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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,308	02/09/2001	Luigi Naldini	40511	7081
7590 01/22/2004				
Gates & Cooper LLP Howard Hughes Center 6701 Center Drive West, Suite 1050 Los Angeles, CA 90045		EXAMINER FALK, ANNE MARIE		
		ART UNIT PAPER NUMBER 1632		

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/581,308

Applicant(s)

NALDINI ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any unexpired patent term adjustment. See 37 CFR 1.704(b).

- ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
- ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

- ☐ Applicant's reply has overcome the following rejection(s): _____.
- ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
- ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
- ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-12.

Claim(s) withdrawn from consideration: _____.

3. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

0. ☐ Other: _____

Anne-Marie Falk
Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

Continuation of 2. Note:

The proposed new claims, if entered, would raise new issues requiring further search and consideration. The new claims combine a number of limitations previously recited in dependent claims. The new claims now require inhibition of HIV replication by administration of an HIV vector lacking a transgene, wherein the vector has an intact 5' HIV LTR, a lentiviral packaging signal sequence, the rev response element, and a polylinker replacing 124 base pairs of nef sequence. The specific treatment effect (i.e. inhibition of HIV replication *in vivo*) in combination with the limitation requiring use of an HIV vector lacking a transgene also raises an issue of enablement. Thus, new grounds of rejection would be required upon entry of the new claims. Furthermore, newly proposed Claim 14 would be subject to a new ground of rejection under 35 U.S.C. 112, second paragraph, for indefiniteness in its recitation of the phrase "wherein the HIV is HIV-1" because the term "HIV" has ambiguous antecedent basis, as it is unclear if it refers to the HIV vector or the HIV of the host infection.

Continuation of 5. does NOT place application in condition for allowance because:

See above.

Applicants' arguments have been fully considered but are moot in view of the fact that the arguments are directed to the newly proposed claims, which have not been entered.

Claims 1-12 remain rejected for reasons of record.